

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Havenga et al.

**Serial No.:** 10/010,645

**Filed:** November 13, 2001

**For:** GENE DELIVERY VECTORS WITH  
CELL TYPE SPECIFICITY FOR  
MESENCHYMAL STEM CELLS

**Confirmation No.:** 4875

**Examiner:** B. Whiteman

**Group Art Unit:** 1645

**Attorney Docket No.:** 2578-5006.1US

**NOTICE OF EXPRESS MAILING**

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Person making Deposit: Chris Haughton

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08A be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicant herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
EP 1 020 529 A2	07/19/2000	Introgen B.V.
EP 1 067 888 A1	01/10/2001	Introgen B.V.
EP 1 279 738 A1	01/29/2003	Crucell Holland B.V.
WO 00/52186 A1	09/08/2000	Introgen B.V.

Other Documents

CONGET, P.A., et al., "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells," 28 EXPERIMENTAL HEMATOLOGY 382-390 (2000).

GOOSSENS, P.H., et al., "Infection Efficiency of Type 5 Adenoviral Vectors in Synovial Tissue Can Be Enhanced With a Type 16 Fiber," 44(3) ARTHRITIS & RHEUMATISM 570-577 (March 2001).

HAVENGA, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," 76(9) JOURNAL OF VIROLOGY 4612-4620 (May 2002).

HAVENGA, M.J.E., et al., "Improved Adenovirus Vectors for Infection of Cardiovascular Tissue," 75(7) JOURNAL OF VIROLOGY 3335-3342 (Apr. 2001).

MARX, J.C., et al., "High-Efficiency Transduction and Long-Term Gene Expression with a Murine Stem Cell Retroviral Vector Encoding the Green Fluorescent Protein in Human Marrow Stromal Cells," 10 HUMAN GENE THERAPY 1163-1173 (May 1, 1999).

OLMSTED-DAVIS, E.A., et al., "Use of a Chimeric Adenovirus Vector Enhances BMP2 Production and Bone Formation," 13 HUMAN GENE THERAPY 133-1347 (July 20, 2002).

Other Documents

ROELVINK, P.W., et al., "Identification of a Conserved Receptor-Binding Site on the Fiber Proteins of CAR-Recognizing Adenoviridae," 286 SCIENCE 1568-1571 (Nov. 1999).

ROELVINK, P.W., et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," 72(10) JOURNAL OF VIROLOGY 7909-7915 (Oct. 1998).

TURGEMAN, G., et al., "Bone Stem Cell Mediated Gene Therapy and Tissue Engineering," 15(7) JOURNAL OF BONE AND MINERAL RESEARCH S196 (Sept. 2000), Abstract.

TURGEMAN, G., et al., "Engineered human mesenchymal stem cells: a novel platform for skeletal cell mediated gene therapy," 3 J. GENE MED. 240-251 (2001).

VIGGESWARAPU, M., et al., "Adenoviral Delivery of LIM Mineralization Protein-1 Induces New-Bone Formation in Vitro and in Vivo," 83-A(3) THE JOURNAL OF BONE & JOINT SURGERY 364-376 (March 2001).

YOTNDA, P., et al., "Efficient infection of primitive hematopoietic stem cells by modified adenovirus," 8(12) GENE THERAPY 930-937 (June 2001).

Partial European Search Report, European Application No. 01202619, dated May 7, 2002 (4 pages).

International Search Report, International Application No. PCT/NL02/00443, dated July 24, 2003 (6 pages).

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants hereby identify the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 2578-3833.5US  
Serial No.: 09/918,029  
Filing Date: July 30, 2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.6US  
Serial No.: 10/038,271  
Filing Date: October 23, 2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.7US  
Serial No.: 10/125,751  
Filing Date: April 18, 2002  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3833.8US  
Serial No.: 10/219,414  
Filing Date: 8/15/2002  
Title: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS

Attorney Docket No.: 2578-3833.9US  
Serial No.: 10/618,526  
Filing Date: July 11, 2003  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840US  
Serial No.: 09/065,752  
Filing Date: April 24, 1998  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840.1US  
Serial No.: 09/900,062  
Filing Date: July 6, 2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3840.2US  
Serial No.: 10/396,548  
Filing Date: March 25, 2003  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3935.1US  
Serial No.: 09/912,552  
Filing Date: July 23, 2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-3955.1US  
Serial No.: 10/136,139  
Filing Date: May 1, 2002  
Title: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY VEHICLE DESIGN AND NUCLEIC ACID TRANSFER

Attorney Docket No.: 2578-3982.2US  
Serial No.: 09/517,898  
Filing Date: March 3, 2000  
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-4038.1US  
Serial No.: 09/549,463  
Filing Date: April 14, 2000  
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4038.2US  
Serial No.: 10/234,007  
Filing Date: September 3, 2002  
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4070.1US  
Serial No.: 09/573,740  
Filing Date: May 18, 2000  
Title: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.: 2578-4075US  
Serial No.: 09/332,803  
Filing Date: June 14, 1999  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4080.1US  
Serial No.: 10/235,175  
Filing Date: September 4, 2002  
Title: TARGETED DELIVERY THROUGH A CATIONIC AMINO ACID TRANSPORTER

Attorney Docket No.: 2578-4123.1US  
Serial No.: 09/953,280  
Filing Date: September 14, 2001  
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-4123.2US  
Serial No.: 09/348,354  
Filing Date: July 7, 1999  
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-4192.1US  
Serial No.: 09/657,492  
Filing Date: September 8, 2000  
Title: MODIFIED ADENOVIRAL VECTORS FOR USE IN GENE THERAPY

Attorney Docket No.: 2578-4215.1US  
Serial No.: 10/231,735  
Filing Date: August 28, 2002  
Title: INTERLEUKIN-3 GENE THERAPY FOR CANCER

Attorney Docket No.: 2578-4230US  
Serial No.: 09/214,836  
Filing Date: October 4, 1999  
Title: MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND VACCINES AGAINST MELANOMA

Attorney Docket No.: 2578-4231US  
Serial No.: 09/444,284  
Filing Date: November 19, 1999  
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR ENDOTHELIAL CELLS

Attorney Docket No.: 2578-4489US  
Serial No.: 09/665,472  
Filing Date: September 20, 2000  
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS

Attorney Docket No.: 2578-4489.1US  
Serial No.: 10/646,449  
Filing Date: August 22, 2003  
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS AND METHODS OF USE

Attorney Docket No.: 2578-4509.1US  
Serial No.: 09/928,262  
Filing Date: August 10, 2001  
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY FOR PRIMARY HUMAN CHONDROCYTES

Attorney Docket No.: 2578-4615.1US  
Serial No.: 10/164,085  
Filing Date: June 4, 2002  
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-4615.2US  
Serial No.: 10/272,041  
Filing Date: October 15, 2002  
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-4622.1US  
Serial No.: 10/432,105  
Filing Date: May 20, 2003  
Title: ADENOVIRAL REPLICONS

Attorney Docket No.: 2578-4843US  
Serial No.: 09/843,894  
Filing Date: 4/27/2001  
Title: AAV VECTOR PRODUCTION

Attorney Docket No.: 2578-5148US  
Serial No.: 10/002,750  
Filing Date: November 15, 2001  
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-5226US  
Serial No.: 10/040,949  
Filing Date: January 7, 2002  
Title: INFECTION WITH CHIMAERIC ADENOVIRUSES OF CELLS NEGATIVE FOR THE ADENOVIRUS SEROTYPE 5 COXSACKI ADENOVIRUS RECEPTOR (CAR)

Attorney Docket No.: 2578-5233US  
Serial No.: 10/042,770  
Filing Date: January 9, 2002  
Title: GENE THERAPY FOR ENHANCING AND/OR INDUCING ANGIOGENESIS

Attorney Docket No.: 2578-5233.1US  
Serial No.: 10/224,249  
Filing Date: August 19, 2002  
Title: GENE THERAPY FOR ENHANCING AND/OR INDUCING ANGIOGENESIS

Attorney Docket No.: 2578-5592US  
Serial No.: 10/305,435  
Filing Date: November 25, 2002  
Title: METHODS AND MEANS FOR ENHANCING SKIN TRANSPLANTATION USING GENE DELIVERY VEHICLES HAVING TROPISM FOR PRIMARY FIBROBLASTS, AS WELL AS OTHER USES THEREOF (PRIMAIRE FIBROBLASTEN)

Attorney Docket No.: 2578-5832US  
Serial No.: 10/381,088  
Filing Date: 3/20/2003  
Title: ADENOVIRAL VECTORS PROVIDED WITH A TROPISM FOR DENDRITIC CELLS

Attorney Docket No.: 2578-5904US  
Serial No.: 10/381,857  
Filing Date: March 26, 2003  
Title: ADENOVIRAL VECTORS FOR GENE DELIVERY IN SKELETAL MUSCLE CELLS OR MYOBLASTS

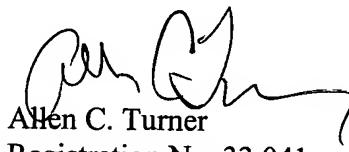
Attorney Docket No.: 2578-6077US  
Serial No.: 10/644,256  
Filing Date: August 20, 2003  
Title: EFFICIENT PRODUCTION OF IgA IN RECOMBINANT MAMMALIAN CELLS

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Respectfully submitted,



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Date: September 30, 2003  
ACT/jml

Enclosures: Form PTO/SB/08A  
Cited Documents  
Check in the amount of \$180.00



PTO/SB/08A (10-01)

PI-08A (0-01)  
Approved for use through 10/31/2003, OMB 0651-0031

Approved for use through 10/31/2002. OMB 0631-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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~~Substitute for form 1449A/PTO~~

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

<i>Complete if Known</i>	
Application Number	10/010,645
Filing Date	November 13, 2001
First Named Inventor	Havenga et al.
Group Art Unit	1645
Examiner Name	B. Whiteman
Attorney Docket Number	2578-5006.IUS

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**U.S. PATENT DOCUMENTS**

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## FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08B(10-01)

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/010,645
<i>(use as many sheets as necessary)</i>				Filing Date	November 13, 2001
Sheet	2	of	3	First Named Inventor	Havenga et al.
				Group Art Unit	1645
				Examiner Name	B. Whiteman
				Attorney Docket Number	2578-5006 IJIS

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
		CONGET, P.A., et al., "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells," 28 EXPERIMENTAL HEMATOLOGY 382-390 (2000).		
		GOOSSENS, P.H., et al., "Infection Efficiency of Type 5 Adenoviral Vectors in Synovial Tissue Can Be Enhanced With a Type 16 Fiber," 44(3) ARTHRITIS & RHEUMATISM 570-577 (March 2001).		
		HAVENGA, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," 76(9) JOURNAL OF VIROLOGY 4612-4620 (May 2002).		
		HAVENGA, M.J.E., et al., "Improved Adenovirus Vectors for Infection of Cardiovascular Tissue," 75(7) JOURNAL OF VIROLOGY 3335-3342 (Apr. 2001).		
		MARX, J.C., et al., "High-Efficiency Transduction and Long-Term Gene Expression with a Murine Stem Cell Retroviral Vector Encoding the Green Fluorescent Protein in Human Marrow Stromal Cells," 10 HUMAN GENE THERAPY 1163-1173 (May 1, 1999).		
		OLMSTED-DAVIS, E.A., et al., "Use of a Chimeric Adenovirus Vector Enhances BMP2 Production and Bone Formation," 13 HUMAN GENE THERAPY 133-1347 (July 20, 2002).		
		ROELVINK, P.W., et al., "Identification of a Conserved Receptor-Binding Site on the Fiber Proteins of CAR-Recognizing Adenoviridae," 28 SCIENCE 1568-1571 (Nov. 1999).		
		ROELVINK, P.W., et al., "The Coxsackievirus-Adenovirus Receptor Protein Can Function as a Cellular Attachment Protein for Adenovirus Serotypes from Subgroups A, C, D, E, and F," 72(10) JOURNAL OF VIROLOGY 7909-7915 (Oct. 1998).		
		TURGEMAN, G., et al., "Bone Stem Cell Mediated Gene Therapy and Tissue Engineering," 15(7) JOURNAL OF BONE AND MINERAL RESEARCH S196 (Sept. 2000), Abstract.		
		TURGEMAN, G., et al., "Engineered human mesenchymal stem cells: a novel platform for skeletal cell mediated gene therapy," 3 J. GENE MED. 240-251 (2001).		
		VIGGESWARAPU, M., et al., "Adenoviral Delivery of LIM Mineralization Protein-1 Induces New-Bone Formation in Vitro and in Vivo," 83-A(3) THE JOURNAL OF BONE & JOINT SURGERY 364-376 (March 2001).		

Examiner Signature		Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

<i>Complete if Known</i>	
Application Number	«Patent Application No»
Filing Date	«Patent Filing Date: July 4, 1996»
First Named Inventor	«Inventor Short Form for Applicant»
Group Art Unit	«Patent Group Art Unit»
Examiner Name	«Patent Examiner»
Attorney Docket Number	«Matter Matter ID»

## **OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Signature		Date Considered	
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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